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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/688,481	10/17/2003	Oswaldo da Costa e Silva	16313-0239	3938

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EXAMINER	
COLLINS, CYNTHIA E	
ART UNIT	**PAPER NUMBER**
1638	

DATE MAILED: 08/18/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/688,481	COSTA E SILVA ET AL.	
	Examiner	Art Unit	
	Cynthia Collins	1638	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *20 April 2006*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *21-47* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *21-43,46 and 47* is/are rejected.

7)☒ Claim(s) *44 and 45* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *20 April 2006* is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

The Amendment filed April 20, 2006 has been entered.

Claims 1-20 are cancelled.

Claims 21-47 are new.

Claims 21-47 are pending.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

All previous objections and rejections not set forth below have been withdrawn.

Drawings

Applicants' petition under 37 CFR 1.84 to accept color drawings is granted.

Claim Rejections - 35 USC § 112

Claims 21-43 and 46-47 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention, for the reasons of record set forth in the office action mailed December 29, 2005.

Applicants' arguments filed April 20, 2006 have been fully considered but they are not persuasive.

Applicants point to pages 10-12 and 16 of the specification as supporting the description of the claimed sequences, and maintain that any person skilled in the art would know how to use the sequence information disclosed in the specification, e.g., the nucleotide sequence of SEQ ID

NO:6, to design primers or probes to isolate a nucleic acid, and that it is also well known in the art to sequence the isolated nucleic acid and perform the sequence homology analysis to determine if the isolated nucleic acid has at least 90% sequence identity to SEQ ID NO:6, or encoding a polypeptide having at least 90% sequence identity to SEQ ID NO:11. Applicants also point out that they have canceled claim 13 drawn to isolated nucleic acids that hybridize under stringent conditions to SEQ ID NO:6. (reply pages 7-8)

Applicants' arguments are inapposite to the outstanding rejection. The outstanding rejection was not predicated on Applicants' failure to provide verbatim support in the specification for the language recited in the rejected claims, or on whether the claimed sequences are enabled. The outstanding rejection was predicated on Applicants' failure to describe a representative number of species falling within the scope of the claimed genus which encompasses numerous undisclosed and uncharacterized variant nucleotide and amino acid sequences, and the structural features unique to the genus.

Further, the Examiner maintains that whether a sequence is described is not dependent on whether the specification provides an enabling disclosure. See *University of California v. Eli Lilly*, 119 F.3d 1559, 43 USPQ 2d 1398 (Fed. Cir. 1997), which discusses the description of a claimed human cDNA sequence based on the disclosure of a rat cDNA sequence and a method for obtaining the human cDNA sequence:

> The patent describes a method of obtaining this cDNA by means of a constructive example, Example 6. This example, however, provides only a general method for obtaining the human cDNA (it incorporates by reference the method used to obtain the rat cDNA) along with the amino acid sequences of human insulin A and B chains. Whether or not it provides an enabling disclosure, it does not provide a written description of the cDNA encoding human insulin, which is necessary to provide a written description of the subject matter of claim 5. The name cDNA is not itself a written description of that DNA; it conveys no distinguishing information concerning its identity. While the example provides a process for obtaining human insulin-encoding

> cDNA, there is no further information in the patent pertaining to that cDNA's relevant structural or physical characteristics; in other words, it thus does not describe human insulin cDNA. Describing a method of preparing a cDNA or even describing the protein that the cDNA encodes, as the example does, does not necessarily describe the cDNA itself. (*Lilly*, 43 USPQ2d at 1405)

In the instant case, while the specification provides a process for obtaining variant nucleotide and amino acid sequences, there is no further information in the specification pertaining to the relevant structural or physical characteristics of these nucleic acids and polypeptides; in other words, it thus does not describe polynucleotides having at least 90% sequence identity to SEQ ID NO:6 or encoding a polypeptide having at least 90% sequence identity to SEQ ID NO:11 or polynucleotides hybridizing thereto under defined stringency conditions wherein the polynucleotides encode a polypeptide that functions to increase a plant cell's tolerance to drought stress and low temperature. Further, describing methods for preparing these nucleic acids does not necessarily describe their nucleotide sequences or the amino acid sequences they encode.

Claims 21-43 and 46-47 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a nucleic acid of SEQ ID NO:6 or a nucleic acid encoding SEQ ID NO:11, and for a transgenic plant or plant cell transformed with a construct comprising a nucleic acid of SEQ ID NO:6 or a nucleic acid encoding SEQ ID NO:11 operably linked to a promoter in a sense orientation, said plant exhibiting increased tolerance to drought or freezing stress, and methods of making said plants and cells, does not reasonably provide enablement for other types of nucleic acids, or for transgenic plant or plant cell transformed with other types nucleic acids. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in

scope with these claims, for the reasons of record set forth in the office action mailed December 29, 2005.

Applicants' arguments filed April 20, 2006 have been fully considered but they are not persuasive.

Applicants point out that it is well known in the art that 90% sequence identity is a relatively high homology standard, and maintain that, without undue experimentation, a person skilled in the art would be able to select polynucleotides having at least 90% sequence identity to SEQ ID NO:6 (or encoding a polypeptide having at least 90% sequence identity to SEQ ID NO:11) that would retain the function of a CCSRP (e.g., a protein as defined in SEQ ID NO:11) by analyzing the sequences utilizing the information disclosed in the specification, such as the "conservative amino acid substitution" technique described at page 21. Applicants also maintain that by further performing the routine screening assay as described in the specification, such as Example 7, a person skilled in the art would know which polynucleotides having at least 90% sequence identity to SEQ ID NO:6 (or encoding a polypeptide having at least 90% sequence identity to SEQ ID NO:11) would confer stress tolerance to a plant upon transformation. Applicants further point out that they have canceled claims 3, 13 and 19 drawn to isolated nucleic acids that hybridize under stringent conditions to SEQ ID NO: 6. (reply pages 8-9)

Applicants' arguments are inapposite to the outstanding rejection. The outstanding rejection was not predicated on Applicants' failure to provide guidance with respect to techniques that were known to and within the abilities of one skilled in the art at the time of filing. The outstanding rejection was predicated on Applicants' failure to provide guidance with respect to which variant nucleic acid sequences can be used to increase the tolerance of a plant cell transformed therewith to drought stress and low temperature. Such guidance is necessary

because the function of nucleic acid sequences that hybridize under stringent conditions to SEQ ID NO:6 or that have at least 90% sequence identity to SEQ ID NO:6 or that encode polypeptides having at least 90% sequence identity with SEQ ID NO:11 is unpredictable, since structurally homologous sequences are not always functionally homologous. In the instant case the specification discloses only a single nucleotide sequence (SEQ ID NO:6) that both meets the structural limitations set forth in the claims and functions to increase the tolerance of a plant cell transformed therewith to drought stress and low temperature, and the prior art of record is free of SEQ ID NO:6 and such variants. Accordingly neither the specification nor the prior art of record establish that a variant sequence that meets the structural limitations set forth in the claims and retains the specific activity of SEQ ID NO:6 could be identified without undue experimentation by merely performing the routine screening assay as described in the specification.

The Examiner also maintains that it is not well known in the art that 90% sequence identity is a relatively high homology standard for the claimed sequences, as the claimed sequences are not known in the art.

The Examiner further maintains that the "conservative amino acid substitution" technique described at page 21 does not provide the required guidance, as a conservative amino acid substitution does not necessarily produce a variant protein that has the same function as the nonvariant protein.

See, for example, Hill M.A. et al (Functional analysis of conserved histidines in ADP-glucose pyrophosphorylase from *Escherichia coli*. Biochem Biophys Res Commun. 1998 Mar 17;244(2):573-7), who teach that when two of three histidines that are maintained in ADP-glucose pyrophosphorylase across several species are substituted with the "nonconservative" amino acid glutamine, there is little effect on enzyme activity, while the substitution of one of

those histidines with the "conservative" amino acid arginine drastically reduces enzyme activity (see Table 1).

Allowable Subject Matter

Claims 44-45 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Remarks

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Cynthia Collins whose telephone number is (571) 272-0794. The examiner can normally be reached on Monday-Friday 8:45 AM -5:15 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anne Marie Grunberg can be reached on (571) 272-0975. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Cynthia Collins
Primary Examiner
Art Unit 1638

CC

6/29/06

ANNE MARIE GRUNBERG
SUPERVISORY PATENT EXAMINER